

## **REMARKS / ARGUMENTS**

### **Status of Claims**

Claims 1-8, 11-13, 46 and 47 are pending in the application. Claims 1-8, 11-13, 46 and 47 stand rejected. Applicants have amended Claims 1 and 11, leaving Claims 1-8, 11-13, 46 and 47 for consideration upon entry of the present Amendment.

Applicants appreciate the Examiner taking the time to talk with the Applicants attorney on October 2, 2009 to discuss the prior art and clarify limitations in the claims.

Applicants respectfully submit that the rejections under 35 U.S.C. §112 second paragraph and 35 U.S.C. §103(a) have been traversed, that no new matter has been entered, and that the application is in condition for allowance.

### **Rejections Under 35 U.S.C. §112, Second Paragraph**

Claim 12 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

The Examiner finds that there is insufficient antecedent basis for the limitation “the geometric landmark.” In addition, the Examiner finds that it is unclear whether this limitation is intended to refer to the previously mentioned geometric marker or anatomical landmark.

By this Amendment, Applicants have amended Claim 12 to read:

" . . . and each of the geometric markers in an opaque fashion, wherein each of said geometric markers has a different degree of translucency."

Applicants respectfully submit that antecedent basis for this amendment may be found in Paragraph [0034] of the application as originally filed. In view of the foregoing, Applicants respectfully submit that the claimed subject matter is described in such a manner that reasonably conveys to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection, which Applicants consider to be traversed.

**Rejections Under 35 U.S.C. §103(a)**

Claims 1-13 and 46-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Keidar et al. (U.S. Patent 6650927, hereinafter “Keidar”) in view of Subramanyan et al. (U.S. Patent 6782284, hereinafter “Subramanyan”), Chen et al. (WO 96/10949, hereinafter “Chen”) and Vesely et al (U.S. Patent 6,248,898, hereinafter “Vesely”).

The Examiner finds that it would be obvious to one of ordinary skill in the art at the time the invention was made to have used the combined system of Keidar, Subramanyan and Chen for location and navigation of an interventional tool as taught by Vesely.

Applicants traverse these rejections for the following reasons.

Applicants respectfully submit that the obviousness rejection based on the References is improper as the References fail to teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed.

Cir. 1988). The Examiner must meet the burden of establishing that all elements of the invention are taught or suggested in the prior art. MPEP §2143.03.

Dependent claims inherit all of the limitations of the respective parent claim and any intervening claim.

Applicants submit that Claim 1 is not obvious in light of the proposed combination of Keidar, Subramanyan, Chen and Vesely. In the office action, the Examiner states that Keidar discloses a method for generating a 3D model for use in cardiac interventional planning procedures (such as ventricular pacing planning or atrial fibrillation planning). [Paper 20090706, Page 3]. Applicants respectfully disagree. Applicants find that Keider teaches a process of "generating a 3D geometrical map of the structure using a probe inserted into the structure" (col. 2, lines 50-51), and "sensors used in catheter 20" (col. 5, lines 17-18). Keider does not disclose, teach or suggest an imaging system for a "bi-ventricular pacing planning, an atrial fibrillation planning, and an atrial flutter planning procedure prior to an actual medical interventional procedure."

Applicants submit that since the image is used in a planning procedure, then the image data must have been pre-acquired. Therefore 3D images can be used to register and subsequently navigate the tools to the desired locations rather than being limited to the pathway over which the tool has traveled as taught by Vesely. Accordingly, Applicants respectfully submit that claimed combination of Claim 1 provides a synergistic effect that is not disclosed, taught, or suggested by the prior art.

Further, independent Claim 1 includes the limitation that the post-processing system is adapted to display at least three geometric markers at associated anatomical landmarks. In the office action, the Examiner maintains the position that the transducer taught by Vesely is an anatomical landmark. [Paper 20090706, page 5]. The Examiner further argues that "as known in the art" an anatomical landmark can be used to refer to

either an actual body part or a marker placed on the body part. Applicants continue to respectfully disagree. As the Applicants have previously argued, the transducer is a foreign object inserted into a person's body. The term anatomical in contrast refers to a structural makeup of the patient or the patient's parts. [See "anatomy." Merriam-Webster Online Dictionary. 2009. Merriam-Webster Online. 17 February 2009 <<http://www.merriam-webster.com/dictionary/anatomy>>]. Applicants respectfully submit that the argument put forth by the Examiner that a transducer is an anatomical structure is contrary to the well-known and accepted usage of the term "anatomical".

Nevertheless, in an attempt to advance prosecution of the present application, Applicants have amended Claim 1 to clarify that "the post processing system is further adapted to display at least three geometric markers, each of the markers, each of the three geometric markers associated with anatomical landmarks in the volume of cardiac image data." Applicants respectfully submit that the limitation of cardiac image data further clarifies that the anatomic landmarks are in the cardiac image, meaning part of the patient's physical cardiac structure, and not a foreign object.

Applicants further submit that Keidar, Subramanyan, and Chen fail to cure this deficiency and therefore the proposed combination would fail to operate in the same manner as the claimed invention. Accordingly, Applicants respectfully submit that independent Claim 1 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely.

Applicants further reassert arguments that were previously presented that Vesely describes a real-time ultrasound technique. In this technique sound waves are used to track real-time location of cardiac needles, probes catheters etc. Vesely also discloses that transducers are energized to yield signals with respect to the field of view, and no fixation on anatomical landmarks. Applicants submit that utilization of reference locations taught by Vesely are at a greater distance from the points of interest which could introduce variability and motion if the reference points are relocated relative to the interventional tool. Therefore, the operator is limited to being able to acquire/reference/visualize only

that anatomical pathway over which the tool has traveled. Thus the actual patient vascular opening and dimensions may be lost and can result in false security for the operator, meaning that if the actual vessel is in a different location, interventional activities will be performed at suboptimal locations.

Applicants submit that the transducers are not part of the patient's body and therefore not a fixed structure like an anatomical structure of the patient's body. Due to the complexity of the human body and its reaction to foreign bodies, the transducers would move over time. As such, one of ordinary skill in the art would not want to rely upon such devices as landmarks in the procedure planning system of Claim 1 due to the variability they would induce. This variability is not an issue in the device taught by Vesely because the Vesely device is used in real-time, not as a procedure planning system acquired prior to an actual medical interventional procedure. Applicants submit that because of the variability in the proposed combination, common sense would steer a person of ordinary skill in the art away from such usage and reliance, not toward it.

Applicants respectfully submit that combination of Keidar, Subramanyan and Chen and Vesely fail to teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

With respect to dependent Claims 2-8, which depend directly or indirectly from independent Claim 1, also incorporate all of the limitations of the parent claim. As such, for at least the reasons set forth above, Applicant submits that Claims 2-8 are not obvious view of Keidar, in light of Subramanyan, Chen and Vesely. Reconsideration and withdrawal of this rejection is respectfully requested.

With respect to dependent Claim 13, which depends from independent Claim 1, therefore incorporates all of the limitations of Claim 1. Accordingly, for at least the reasons set forth above with respect to Claim 1, Applicants submit that dependent Claim

13 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely. Further, Applicants submit that Claim 13 also includes limitations not found in the prior art. Claim 13 includes the limitation that the post-processing system displays a first image of at least one of the heart, coronary sinus, left ventricle, left atrium, and right atrium in one of a translucent fashion and an opaque fashion while a second image of the coronary sinus is displayed in one of the translucent fashion and opaque fashion opposite the first image.

In the office action, the Examiner cites to Keidar, column 5 and 8, and Figures 6-7 in support of the rejection. [Paper 20090706, Page 6]. Applicants respectfully disagree. Applicants find that Keidar discloses the displaying/superimposing of diagnostic data (e.g. metabolic factors) and use of different colors. Applicants find no disclosure or suggestion of displaying one image of the heart, coronary sinus, left ventricle, left atrium in a translucent fashion and an opaque fashion while a second image of the coronary sinus is displayed in one of the translucent fashion and opaque fashion opposite the first image. Therefore, the proposed combination Keidar, Subramanyan, Chen and Vesely fails to provide the advantages of allowing the operator to view one portion of the heart (e.g. coronary sinus) in the context of the entire heart as described in Paragraph [0034] of the Present Application.

Accordingly, Applicants respectfully submit that a prima facie case of obviousness has not been established and that none of the references teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. Accordingly, Applicants respectfully submit that dependent Claim 13 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely.

Applicants respectfully submit that independent Claim 11 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely. As with Claim 1, Claim 11 includes the limitations of a cardiac image data that has been stored in a database and the image is viewable in at least one of a bi-ventricular pacing, atrial fibrillation and atrial flutter planning procedure and that the post-processing system is adapted to display at least three

geometric markers associated with anatomical landmarks in the volume of cardiac image data. Therefore, Applicants submit that for the reasons set forth above with respect to independent Claim 1, Claim 11 is not obvious in view of the proposed combination of Keidar, in light of Subramanyan, Chen and Vesely.

With respect to dependent Claim 12, which depends from independent Claim 11, therefore incorporates all of the limitations of Claim 11. Accordingly, for at least the reasons set forth above with respect to Claim 11, Applicants submit that dependent Claim 12 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely. Applicants further submit that Claim 12 also includes limitations not found in the prior art. Claim 12 includes the limitation that the coronary sinus is displayed in a translucent fashion and the geometric markers in an opaque fashion. As discussed above with respect to Claim 13, Applicants find that neither Keidar nor any of the other cited references disclose or suggest such a limitation.

Accordingly, Applicants respectfully submit that a prima facie case of obviousness not been established and that none of the references teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. Accordingly, Applicants respectfully submit that dependent Claim 12 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely.

With respect to independent Claim 46, which includes all of the limitations of Claim 1, including the limitation that the post-processing system inserts at least three geometric markers at corresponding anatomical landmarks in the cardiac image data. For the same reasons set forth above with respect to Claim 1, Applicants respectfully submit that none of the references teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. Accordingly, Applicants respectfully submit that independent Claim 46 is not obvious in view of Keidar, in light of Subramanyan, Chen and Vesely.

In addition to the foregoing, Applicants find no motivation or teaching in any of the References to modify a primary Reference in view of its respective secondary Reference to arrive at the claimed arrangement of elements without disturbing the accuracy characteristics of the three-dimensional models of the actual patient for use in planning and intended purpose of the art being modified.

In view of the foregoing, Applicants submit that the References fail to teach or suggest each and every element of the claimed invention and are therefore wholly inadequate in their teaching of the claimed invention as a whole, fail to motivate one skilled in the art to do what the patent Applicants have done, fail to recognize a problem recognized and solved only by the present invention, fail to offer any reasonable expectation of success in combining the References to perform as the claimed invention performs, fail to teach a modification to prior art that does not render the prior art being modified unsatisfactory for its intended purpose, and discloses a substantially different invention from the claimed invention, and therefore cannot properly be used to establish a prima facie case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §103(a), which Applicants consider to be traversed.

In light of the foregoing, Applicants respectfully submit that the Examiner's rejections under 35 U.S.C. §103(a), have been traversed, and respectfully requests that the Examiner reconsider and withdraw these rejections.



If a communication with Applicants' Attorneys would assist in advancing this case to allowance, the Examiner is cordially invited to contact the undersigned so that any such issues may be promptly resolved.

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 07-0845.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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